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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,084	02/08/2002	Jose V. Torres	3648.032	9437
7590	12/15/2003			EXAMINER
PENDORF & CUTLIFF			BYRD, DEVON R	
P.O. Box 20445				
Tampa, FL 33622-0445			ART UNIT	PAPER NUMBER
			1639	
DATE MAILED: 12/15/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/072,084	TORRES, JOSE V.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Devon R Byrd	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 08 February 2002.
- 2a)  This action is **FINAL**.                                    2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) \_\_\_\_\_ is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) 1-31 are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a)  All    b)  Some \* c)  None of:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - a)  The translation of the foreign language provisional application has been received.
- 14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4)  Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other: \_\_\_\_\_.

## DETAILED ACTION

*STATUS OF THE CLAIMS*

CLAIMS 1-31 ARE PENDING IN THE PRESENT APPLICATION AND ARE SUBJECT TO RESTRICTION AND ELECTION OF SPECIES REQUIREMENTS.

*ELECTION/RESTRICTIONS*

RESTRICTION TO ONE OF THE FOLLOWING INVENTIONS IS REQUIRED UNDER 35 U.S.C.

121:

- I. CLAIMS 1-16, DRAWN TO A PROCESS FOR PREPARATION OF AN IMMUNOGENIC PEPTIDE MIXTURE, CLASSIFIED IN CLASS 530, SUBCLASS 333+.
- II. CLAIMS 17-19, DRAWN TO A PEPTIDE MIXTURE IMMUNOGENIC TO A PATHOGEN, CLASSIFIED IN CLASS 514, SUBCLASS 2.
- III. CLAIM 20, DRAWN TO A LIPID-CONJUGATED PEPTIDE COMPOSITION, CLASSIFIED IN CLASS 424, SUBCLASS 283.1.
- IV. CLAIM 21, DRAWN TO A CARRIER PROTEIN-CONJUGATED PEPTIDE COMPOSITION, CLASSIFIED IN CLASS 424, SUBCLASS 192.1.
- V. CLAIMS 22-25, DRAWN TO A METHOD VACCINATION AGAINST A PATHOGEN, CLASSIFIED IN CLASS 424, SUBCLASS 185.1.
- VI. CLAIM 26, DRAWN TO A METHOD OF DIAGNOSING INFECTION OF A SUBJECT BY A PATHOGEN, CLASSIFIED IN CLASS 436, SUBCLASS 536.
- VII. CLAIM 27, DRAWN TO A DIAGNOSTIC KIT FOR DETERMINING INFECTION OF A SUBJECT BY A PATHOGEN, CLASSIFIED IN CLASS 435, SUBCLASS 7.1.
- VIII. CLAIM 28, DRAWN TO A PROCESS FOR ISOLATING AN ANTIBODY IMMUNOGENIC TO A PATHOGEN, CLASSIFIED IN CLASS 424, SUBCLASS 280.1.

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IX. CLAIMS 29 AND 30, DRAWN TO A PROCESS FOR ISOLATING A GENE OR GENE FRAGMENT, CLASSIFIED IN CLASS 435, SUBCLASS 6.

X. CLAIM 31, DRAWN TO AN IMMUNOTHERAPY AGAINST A PATHOGEN, CLASSIFIED IN CLASS 514, SUBCLASS 2.

RESTRICTION IS DEEMED PROPER BECAUSE THE ABOVE METHODS CONSTITUTE PATENTABLY DISTINCT INVENTIONS FOR THE FOLLOWING REASONS: GROUPS I, V, VI, AND VIII-X ARE DIRECTED TO METHODS THAT RECITE STRUCTURALLY AND FUNCTIONALLY DISTINCT ELEMENTS, ARE NOT REQUIRED FOR ONE ANOTHER, AND ACHIEVE DIFFERENT GOALS. IN THE INSTANT CASE, GROUP I REQUIRES OBTAINING IMMUNOGENIC EPITOPE SEQUENCES OF A PATHOGEN, WHICH IS NOT REQUIRED BY ANY OF THE OTHER GROUPS. GROUP V REQUIRES THE STEP OF ADMINISTERING TO A SUBJECT AN EFFECTIVE AMOUNT OF A VACCINE, WHICH IS NOT REQUIRED BY ANY OF THE OTHER GROUPS. GROUP VI REQUIRES OBTAINING AN ANTIBODY-CONTAINING BIOLOGICAL SAMPLE FROM SAID SUBJECT, WHICH IS NOT REQUIRED BY ANY OF THE OTHER GROUPS. GROUP VIII IS DIRECTED TO THE ISOLATION OF AN ANTIBODY, WHICH IS NOT THE GOAL OF THE OTHER GROUPS. GROUP IX REQUIRES THE ISOLATION OF A NUCLEIC ACID MOLECULE, WHICH IS NOT REQUIRED BY ANY OF THE OTHER GROUPS. GROUP X REQUIRES ADMINISTRATION OF A PEPTIDE OR PROTEIN ENCODED BY A PORTION OF A GENE OR GENETIC MATERIAL, WHICH IS NOT REQUIRED BY ANY OF THE OTHER GROUPS.

RESTRICTION IS DEEMED PROPER BECAUSE THE ABOVE INVENTIVE GROUPS ARE DIRECTED TO DIFFERENT PRODUCTS, AND THESE PRODUCTS CONSTITUTE PATENTABLY DISTINCT INVENTIONS FOR THE FOLLOWING REASONS: GROUPS II, III, IV, AND VII ARE DIRECTED TO PRODUCTS THAT ARE DISTINCT BOTH PHYSICALLY AND FUNCTIONALLY, ARE NOT REQUIRED FOR ONE ANOTHER, AND ARE THEREFORE PATENTABLY DISTINCT. GROUP III REQUIRES A CONJUGATED LIPID MOIETY, WHICH IS

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NOT REQUIRED FOR ANY OF THE OTHER GROUPS. GROUP IV REQUIRES A CONJUGATED CARRIER PROTEIN MOIETY, WHICH IS NOT REQUIRED FOR ANY OF THE OTHER GROUPS. GROUP VII REQUIRES DIRECTIONS FOR EVALUATING AN IMMUNOGENIC RESPONSE OF AN ANTIBODY-CONTAINING BIOLOGICAL SAMPLE, WHICH IS NOT REQUIRED FOR ANY OF THE OTHER GROUPS.

THE COMPOSITIONS OF GROUPS II-IV AND VII, AND THE METHODS OF GROUPS I, V, VI, AND VIII-X REPRESENT DIFFERENT STATUTORY CLASSES OF INVENTIONS. THESE INVENTIONS ARE PATENTABLY DISTINCT FOR THE FOLLOWING REASONS. THE COMPOSITIONS OF SAID GROUPS CAN BE USED IN MATERIALLY DIFFERENT PROCESSES (I.E., IN THE THERAPEUTIC METHOD OF CLAIM 31 VERSUS THE DIAGNOSTIC METHOD OF CLAIM 26). FURTHERMORE, THE METHODS OF SAID GROUPS COULD BE PRACTICED WITH MATERIALLY DIFFERENT COMPOSITIONS (I.E., USING AN INTACT PATHOGEN OR PATHOGEN EXTRACT).

BECAUSE THESE INVENTIONS ARE DISTINCT FOR THE REASONS GIVEN ABOVE, AND

- A. HAVE ACQUIRED A SEPARATE STATUS IN THE ART AS SHOWN BY THEIR DIFFERENT CLASSIFICATION;
- B. HAVE DIFFERENT AND SEPARATELY BURDENSONE MANUAL AND/OR COMPUTER STRUCTURE, NAME, AND BIBLIOGRAPHICAL SEARCHES; AND,
- C. HAVE DIVERGENT SUBJECT MATTER, RESTRICTION FOR EXAMINATION PURPOSES AS INDICATED IS PROPER.

APPLICANT IS ADVISED THAT THE REPLY TO THIS REQUIREMENT TO BE COMPLETE MUST INCLUDE AN ELECTION OF THE INVENTION TO BE EXAMINED EVEN THOUGH THE REQUIREMENT BE TRAVERSED (37 CFR 1.143).

*ELECTION OF SPECIES*

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THIS APPLICATION CONTAINS CLAIMS RECITING GENERIC CATEGORIES THAT READ ON A PLURALITY OF PATENTABLY DISTINCT SPECIES. FOR PURPOSES OF SEARCH, APPLICANT IS REQUIRED TO ELECT A SINGLE SPECIFIC REPRESENTATIVE SPECIES FOR EACH OF THE FOLLOWING GENERIC CATEGORIES:

- A) A PATHOGEN (GROUPS I, II AND V-X)
- B) A PATHOGENIC DISEASE (GROUP V)
- C) A BIOINFORMATICS METHODOLOGY (GROUP I)
- D) A LIPID MOIETY (GROUP III)
- E) A CARRIER PROTEIN MOIETY (GROUP IV)

APPLICANT IS REQUIRED UNDER 35 U.S.C. 121 TO ELECT A SINGLE SPECIES, EVEN THOUGH THIS REQUIREMENT IS TRAVERSED.

THE SPECIES MENTIONED ABOVE HAVE DIFFERENT AND SEPARATELY BURDENOME MANUAL AND/OR COMPUTER STRUCTURE, NAME, AND BIBLIOGRAPHICAL SEARCHES, AND HAVE DIVERGENT SUBJECT MATTER.

APPLICANT IS ADVISED THAT A REPLY TO THIS REQUIREMENT MUST INCLUDE AN IDENTIFICATION OF THE SPECIES THAT IS ELECTED CONSONANT WITH THIS REQUIREMENT, AND A LISTING OF ALL CLAIMS READABLE THEREON, INCLUDING ANY CLAIMS SUBSEQUENTLY ADDED. AN ARGUMENT THAT A CLAIM IS ALLOWABLE OR THAT ALL CLAIMS ARE GENERIC IS CONSIDERED NONRESPONSIVE UNLESS ACCOMPANIED BY AN ELECTION.

UPON THE ALLOWANCE OF A GENERIC CLAIM, APPLICANT WILL BE ENTITLED TO CONSIDERATION OF CLAIMS TO ADDITIONAL SPECIES WHICH ARE WRITTEN IN DEPENDENT FORM OR OTHERWISE INCLUDE ALL THE LIMITATIONS OF AN ALLOWED GENERIC CLAIM AS PROVIDED BY 37 CFR 1.141. IF CLAIMS ARE ADDED AFTER THE ELECTION, APPLICANT MUST INDICATE WHICH ARE READABLE UPON THE ELECTED SPECIES. MPEP § 809.02(a).

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SHOULD APPLICANT TRAVERSE ON THE GROUND THAT THE SPECIES ARE NOT PATENTABLY DISTINCT, APPLICANT SHOULD SUBMIT EVIDENCE OR IDENTIFY SUCH EVIDENCE NOW OF RECORD SHOWING THE SPECIES TO BE OBVIOUS VARIANTS OR CLEARLY ADMIT ON THE RECORD THAT THIS IS THE CASE. IN EITHER INSTANCE, IF THE EXAMINER FINDS ONE OF THE INVENTIONS UNPATENTABLE OVER THE PRIOR ART, THE EVIDENCE OR ADMISSION MAY BE USED IN A REJECTION UNDER 35 U.S.C. 103(A) OF THE OTHER INVENTION.

THE INVENTIONS ARE DISTINCT, EACH FROM THE OTHER BECAUSE OF THE FOLLOWING REASONS:

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DEVON R BYRD WHOSE TELEPHONE NUMBER IS 703-305-0159. THE EXAMINER CAN NORMALLY BE REACHED ON MON-FRI 8A-5P.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, ANDREW WANG CAN BE REACHED ON 703-306-2317. THE FAX PHONE NUMBER FOR THE ORGANIZATION WHERE THIS APPLICATION OR PROCEEDING IS ASSIGNED IS 703-308-2742.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE RECEPTIONIST WHOSE TELEPHONE NUMBER IS 703-308-1235.

DB  
DECEMBER 9, 2003

DEVON R. BYRD  
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